

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILIN	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	. CONFIRMATION NO.
10/529,613	06/0	08/2005	Sridhar Kudaravalli	4-32702A 1738	
1095 NOVARTIS	7590	05/07/2007	EXAMINER		
CORPORATE		ECTUAL PROPER	POHNERT, STEVEN C		
ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			ART UNIT	PAPER NUMBER	
2.101111110	7 214 110 07900 10	.,,,,,,	•	1634	
				,	
			,	MAIL DATE	DELIVERY MODE
				05/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)					
		10/529,613	KUDARAVALLI ET AL.					
O	ffice Action Summary	Examiner	Art Unit					
	·	Steven C. Pohnert	1634					
The	MAILING DATE of this communication app							
	Period for Reply							
WHICHEV - Extensions or after SIX (6) - If NO period - Failure to repair any reply rec	ENED STATUTORY PERIOD FOR REPLY ER IS LONGER, FROM THE MAILING DA of time may be available under the provisions of 37 CFR 1.13 MONTHS from the mailing date of this communication. For reply is specified above, the maximum statutory period we ply within the set or extended period for reply will, by statute, be every devived by the Office later than three months after the mailing at term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time iill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status								
1)⊠ Resp	oonsive to communication(s) filed on <u>08 Ju</u>	ne 200 <u>5</u> .						
2a)☐ This	This action is FINAL . 2b) This action is non-final.							
• ——	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Disposition of	f Claims							
4\⊠ Clair	4)⊠ Claim(s) <u>1-19</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.							
6)☐ Clair	Claim(s) is/are rejected.							
7) Clair	n(s) is/are objected to.							
8)⊠ Clair	n(s) <u>1-19</u> are subject to restriction and/or e	election requirement.						
Application P	apers							
9)□ The s	pecification is objected to by the Examine	r:						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The c	oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.					
Priority under	35 U.S.C. § 119							
		priority under 35 H.S.C. & 119(a)	h-(d) or (f)					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:								
1. Certified copies of the priority documents have been received.								
2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage								
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
			•					
Attachment(s)	eferences Cited (PTO-892)	4) Interview Summary	(DTO 412)					
	raftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate					
	Disclosure Statement(s) (PTO/SB/08) /Mail Date	5) Notice of Informal P 6) Other:	atent Application					

Page 2

Application/Control Number: 10/529,613

Art Unit: 1634

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5 and 16 (in part), are drawn to methods of determining the degree of cholesterol elevation due to immunosuppressive by a SNP at -511 of IL-1 β .

Group 2, claim(s) 6-10 and 16 (in part) and, drawn to methods of determining the degree of cholesterol elevation due to immunosuppressive by a SNP at –31 of IL-1β.

Group 3, claim(s) 11-15, are drawn to methods of determining the degree of cholesterol elevation due to immunosuppressive by determining the haplotype of IL-1 β .

Group 4, claim(s) 17 and 19, are drawn to kits of determining the degree of cholesterol elevation due to immunosuppressive by a SNP at –511 of IL-1β.

Group 5, claim(s) 18, is drawn to kits for determining the degree of cholesterol elevation due to immunosuppressive by a SNP at -31 of IL-1 β .

- 2. The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims are drawn to methods of detecting mutation at -511 of IL-1 β gene. Duff et al (US Patent 6,268,142 published July 31, 2001) teaches mutations of the Il-1 β gene including the -511 mutation. As Duff teaches mutations in the IL-1 β gene, the instant inventions lack a special technical feature over the prior art.
- 3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

Application/Control Number: 10/529,613

Art Unit: 1634

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

Application/Control Number: 10/529,613

Art Unit: 1634

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/529,613

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

JEANINE A. GOLDBERG PRIMARY EXAMINER 4/30/07